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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,230	02/25/2004	Tadamitsu Kishimoto	046124-5042-01	1453

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

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04/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,230	KISHIMOTO ET AL.	
	Examiner	Art Unit	
	LAURA B. GODDARD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,26,28 and 31-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,26,28 and 31-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/646,785.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/9/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed January 4, 2010 in response to the Office Action of August 5, 2009, is acknowledged and has been entered. Claims 25, 26, 28, and 31-36 are pending and are currently being examined. Claims 31-26 are new. Claims 1-24, 27, 29, and 30 are canceled.

Maintained Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claims 25, 26, and 28 remain rejected and new claims 31-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection (see section 2 of the previous Office Action).

Response to Arguments

3. Applicants argue that Examiner previously held the pending claims to be in compliance with the written description requirement and the claims have not been

amended since, hence the claims should continue to be in compliance with the written description requirement (p. 4, section I).

The arguments have been considered but are not found persuasive. The prior written description rejection was withdrawn, therefore no longer applies. A new written description rejection was set forth in the previous non-final Office Action, section 2, with different arguments. The new written description rejection set forth new reasons for why the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

4. Applicants argue that In re Alonso is inapplicable to the instant situation and therefore cannot be relied upon to allege that the pending claims lack written description. The specification of Alonso's application does not characterize the antigen to which the monoclonal antibodies must bind; it discloses only the molecular weight of the antigen (a 221 kD tumor surface antigen) in an Example *(see In re Alonso,* pp. 3, 9). Furthermore, the antibody was described in terms of being idiotypic to the neurofibrosarcoma of said human *(see In re Alonso,* p. 9). In other words, *In re Alonso* dealt with an undefined antigen. Alonso's claim to a broad genus of antibodies was held to lack sufficient written description because the application only disclosed an undefined antigen. Applicants argue that in contrast, in the instant application, the antigen is specified *(i.e.* human CXCR4 and human SDF-1). The specification clearly discloses the antigen including the amino acid sequence (see SEQ ID NO: 1 (human CXCR4); SEQ

ID NO: 5, 9 (human SDF-1)). Applicants argue that contrary to the allegations in the Office Action implying that at the time of the invention 12G5 was the only known antibody against CXCR4 (see page 4 of the Office Action), at the time of the invention, numerous antibodies against (1) CXCR-4 *(see e.g.,* Delezay *et al.* (a copy of the Abstract of which is attached); Forster *et al.* (copy of which is attached) and (2) SDF-1 (Imai *et al.* (a copy of which is attached)) were known, some of which were even commercially available. Applicants argue that at the time of the invention, it was also well-known that antibodies can readily be made against a known antigen (p. 4-5), section II).

The arguments have been considered but are not found persuasive. It is noted that at least Alonso produced one species of antibody that functioned to treat a human as claimed and satisfied the written description requirement for that single hybridoma producing that single monoclonal antibody. Unlike in In re Alonso, the specification does not produce even one species of antibody that functions as claimed to inhibit the binding between the human ligand SDF-1 and the human receptor CXCR4 and treat a solid tumor, treat a disease pathologically caused by neovascularization, or suppress vascularization. One of skill in the art would not conclude that Applicants are in possession of the genus of antibodies that function as claimed.

Although Applicants argue that human ligand SDF-1 and the human receptor CXCR4 are two defined antigens known in the art, and the production of antibodies against them is routine, Applicants failed to address any possible support in the specification and the art at the time of filing for antibodies that bind to human ligand

SDF-1 and the human receptor CXCR4 and function to inhibit the binding between the human ligand SDF-1 and the human receptor CXCR4 and treat a solid tumor, treat a disease pathologically caused by neovascularization, or suppress vascularization. While producing antibodies to simply bind SDF-1 or CXCR4 for detection purposes may be known in the art at the time of filing and routine to screen for, the specification fails to provide adequate written description for such antibodies that also function to inhibit the binding between the human ligand SDF-1 and the human receptor CXCR4 and treat a solid tumor, treat a disease pathologically caused by neovascularization, or suppress vascularization. Further, the court found in (*Rochester v. Searle*, 358 F.3d 916, Fed Cir., 2004) that screening assays, are not sufficient to provide written description for an invention because they are merely a wish or plan for obtaining the claimed chemical invention. Screening for antibodies that function to inhibit the binding between the human ligand SDF-1 and the human receptor CXCR4 and treat a solid tumor, treat a disease pathologically caused by neovascularization, or suppress vascularization, is not routine and is a wish or plan for obtaining the claimed invention.

The claims require anti-human ligand SDF-1 and anti-human receptor CXCR4 antibodies to function to inhibit the binding between the human ligand SDF-1 and the human receptor CXCR4 and treat a solid tumor, treat a disease pathologically caused by neovascularization, or suppress vascularization, and the specification does not provide adequate written description for antibodies that function as claimed. Applicants' arguments are drawn only to written description support for antibodies that function to

bind human ligand SDF-1 and the human receptor CXCR4, and binding does not necessitate or necessarily encompass inhibition and treatment as claimed.

Applicants failed to provide copies of Delezay *et al.*, Forster *et al.* and Imai *et al.* therefore Examiner cannot assess these references nor appropriately respond to the arguments addressing them. It is assumed these references disclose antibodies that bind SDF-1 or CXCR4 but do not disclose antibodies that function to inhibit the binding between the human ligand SDF-1 and the human receptor CXCR4 and treat a solid tumor, treat a disease pathologically caused by neovascularization, or suppress vascularization, because Applicants have made no such arguments for support in the art at the time of filing for antibodies that function to inhibit the binding between the human ligand SDF-1 and the human receptor CXCR4 and treat a solid tumor, treat a disease pathologically caused by neovascularization, or suppress vascularization. Contrary to Applicants' assertion, Examiner did not argue that 12G5 was the only known antibody to CXCR4. Examiner provided an example of an antibody known in the art at the time of filing used for detection to demonstrate the state of the art at the time of filing.

5. Applicants argue that SDF-1 or CXCR4 are fully characterized antigens, Applicants provided screening methods to obtain an antibody that functions as claimed, and Applicants described methods of treating, therefore one of skill in the art would reasonably conclude that the inventors were in possession of the claimed invention (Applicants point to Noelle and MPEP 2163) (p. 5-6, section III).

The arguments have been considered but are not found persuasive for the same reasoning above. While the specification provides written description for antibodies that simply bind known antigens SDF-1 or CXCR4, the specification does not provide adequate written description for said antibodies that function to inhibit the binding between the human ligand SDF-1 and the human receptor CXCR4 and treat a solid tumor, treat a disease pathologically caused by neovascularization, or suppress vascularization for the reasons of record. As stated above, contemplating screening assays in the specification is not sufficient to provide written description for an invention because it is merely a wish or plan for obtaining the claimed invention (*Rochester v. Searle*, 358 F.3d 916, Fed Cir., 2004). Screening for antibodies that function to inhibit the binding between the human ligand SDF-1 and the human receptor CXCR4 and treat a solid tumor, treat a disease pathologically caused by neovascularization, or suppress vascularization, is not routine and is a wish or plan for obtaining the claimed invention.

6. Applicants failed to address Examiner's arguments relevant to Lilly and Enzo. The specification does not disclose even one representative species of antibody that functions as claimed. The specification and claims do not define the structural features commonly possessed by members of the antibody genus that can distinguish it from others. There is no recitation or disclosure of structural features common to the members of the antibody genus or which features constitute a substantial portion of the genus. The specification and claims do not identify which structural features are conserved among the claimed antibodies that function to inhibit the binding between the

human ligand SDF-1 and the human receptor CXCR4 and treat a solid tumor, treat a disease pathologically caused by neovascularization, or suppress vascularization or which structures constitute a substantial portion of the genus in order for one to visualize or recognize the identity of the members of the genus, hence the written description for the genus of antibodies in the claimed methods do not meet the standards of Lilly. There are no specific structures, identifying characteristics, partial or complete structures, or known or disclosed structures coupled to the functional characteristic for the broad genus of antibodies that function to inhibit the binding between the human ligand SDF-1 and the human receptor CXCR4 and treat a solid tumor, treat a disease pathologically caused by neovascularization, or suppress vascularization as recited in the claims, hence the specification does not provide adequate written description according to the standards of Enzo. Applicants were not in possession of the genus of antibodies at the time of filing.

7. **Conclusion:** No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. ' 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL

EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. ' 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA B. GODDARD whose telephone number is (571)272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura B Goddard/
Primary Examiner, Art Unit 1642